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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/593,816

09/07/2007

Nitin Bhalachandra Dharmadhikari

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EXAMINER

ALAWADI, SARAH

ART UNIT

PAPER NUMBER

1619

NOTIFICATION DATE

DELIVERY MODE

06/10/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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PPROCESSING@SUGHRUE.COM  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/593,816	<b>Applicant(s)</b> DHARMADHIKARI ET AL.	
	<b>Examiner</b> SARAH AL-AWADI	<b>Art Unit</b> 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 15 is/are pending in the application.
- 4a) Of the above claim(s) 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>09/22/2006 and 08/31/2007</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

**INFORMATION DISCLOSURE STATEMENT**

The Information Disclosure Statements (IDS) filed 09/22/2006 and 08/31/2007 have been acknowledged.

**PRIORITY**

This Application is a 371 of PCT/IN05/00091 filed 03/24/2005. The Examiner acknowledges Applicants claim of foreign priority to 364/MUM/2004 filed 03/25/2004 and 1058/MUM/2004 filed 10/07/2004.

**RESPONSE TO REMARKS OVER RESTRICTION REQUIREMENT**

Applicant's election without traverse of Group I, claims 1-12 and the species of highly swellable polymer in the reply filed on 03/25/2010 is acknowledged.

Claim 15 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 03/25/2010.

***OBJECTION***

Claims 1, 6, and 8 are objected to because of the following informalities: It is believed that Applicants meant to spell “milleu” as milieu. Please correct.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 recite the limitation “a second coating formed by applying a coating composition comprising a film-forming polymer and one or more expandable components on the first coating.” There is insufficient antecedent basis for this limitation in the claim because part (a) does not have a “first coating.”

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Barry et al., PCT/GB88/00779.

The Examiner interprets a film forming polymer in light of the specification which can include that of cellulose derivatives, acrylic acid polymers and copolymers, polymers of acrylic

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acid crosslinked with vinyl glycols and mixtures thereof. Expandable components can include highly swelable grades of cellulose ethers preferably hydroxyethylcellulose, hydroxypropylcellulose, or hydroxypropyl methylcellulose, gums, acrylic acid polymers and copolymers. (MPEP 2111)

Regarding claims 1-12, Barry et al. teach sustained release of therapeutic agents such as nifedipine. The composition comprises a core of nifedipine (therapeutic) and hydroxypropylmethyl cellulose (agent generating internal pressure; expandable component). A coating covering the core comprises water insoluble but swellable acrylic polymers and a hydroxylated cellulose derivative, (expandable components) see abstract. The composition may be in the form of tablets or capsules, see page 7 line 30-34 and page 8 lines 1-6. Regarding the limitations wherein the system is capable of instantaneously floating, contains a flotation time of less than 15 minutes, and wherein the film is capable of expanding and maintaining physical integrity in the gastric milieu; until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed toward a necessary property of the composition which is instantly claimed.

Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Egidio et al. United States Patent, 5,380,533.

The Examiner interprets a film forming polymer in light of the specification which can include that of cellulose derivatives, acrylic acid polymers and copolymers, polymers of acrylic acid crosslinked with vinyl glycols and mixtures thereof. Expandable components can include highly swelable grades of cellulose ethers preferably hydroxyethylcellulose,

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hydroxypropylcellulose, or hydroxypropyl methylcellulose, gums, acrylic acid polymers and copolymers and an expandable component as being directed towards this... (MPEP 2111)

Regarding claims 1-12, Egidio et al. teaches pharmaceutical formulations for oral administration which are coated with a gastroresistant film. The formulations include gastroresistant tablets, gastroresistant capsules containing granulates, or soft and hard gelatine capsules containing gastroresistant granulates, see abstract. The first coating (film forming polymer) consists of Hydroxypropylmethyl cellulose. (highly swellable polymer). Egidio et al. teaches the coating creates a film. (column 4, line 10) Furthermore, Egidio et al. teaches that many coating substances can be used to obtain an enterosoluble gastroresistant coating such as EUDGRAGIT and hydroxypropyl methylcellulose phthalate, see column 4, lines 12-20. The composition further comprises a gastroresistant film coating comprising one or more coating substances with one or more plasticizers, see column 5 lines 1-5. The coating substances include hydroxypropylmethyl cellulose and methacrylic acid, see claims 1, 2, 5 and 7. Regarding the limitations wherein the agent in the core is capable of generating internal pressure on the coat, wherein the expandable components on the tablet core forms a film capable of expanding and maintaining its physical integrity in the gastric milieu; and the flotation time; until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed toward the gastric retention system which is instantly claimed.

### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah Al-Awadi whose telephone number is (571) 270-7678.

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The examiner can normally be reached on 9:30 am - 6:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bonnie Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SARAH AL-AWADI/  
Examiner, Art Unit 1619

/Shanon A. Foley/

Primary Examiner, Art Unit 1619